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US COPD Coalition Comments: Supporting FDA Draft Guidance “Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs”

Background

The U.S.COPD Coalition(USCC) respectfully submits the following comments to the Food and Drug Administration’s (FDA) request for input regarding draft guidance for industry entitled “Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices , and Trial Designs (hereafter “Enhanced Diversity”).

The U.S. COPD Coalition (USCC) is a nonprofit, 501c3 corporation comprised primarily of patient advocates, state coalitions, and health professional organizations. USCC also welcomes individual members, as well as government agency liaisons who work together to advocate for the unmet needs of individuals affected by Chronic Obstructive Pulmonary Disease (COPD), in collaboration with other chronic lung disease groups.

Recommendation

The USCC believes that these recommendations are an important step forward in having the groups of patients studied in clinical trials more accurately reflect the diversity of patients who may benefit from the treatments being trialed. The US COPD Coalition strongly supports the adoption of the Enhanced Diversity Draft Guidance.

Background

Millions of Americans suffer from COPD and other lung and health conditions. There are a huge number of clinical trials currently underway and slotted for the future. The National Heart Lung and Blood Institute (NHLBI) states that COPD is the third leading cause of death among chronic diseases and has been diagnosed in over 16 million Americans and another 16 million are estimated to be undiagnosed. The Centers for Disease Control and Prevention (CDC) estimates over 25 million Americans suffer from asthma, including over 8 million children.¹

It is estimated that about 1 in 4 of those with COPD have never smoked, yet nearly all clinical trials only include current or former smokers.¹ In addition, between 2.1% and 55% of people who have obstructive lung disease have asthma-COPD overlap syndrome (ACOS), depending on the diagnostic criteria used.²

In study after study of COPD medications, patients who have never smoked and patients who have asthma and COPD are routinely excluded from clinical trials. Because they may not be included in, or are under-represented in clinical trials, researchers, doctors, payers, and patients have a limited idea of how patients who have these characteristics will react to the treatments after receiving FDA approval for sale as another available treatment.

This makes it impossible for patients and providers to make informed choices as to how patients with these different characteristics will react to the treatments, since they have specifically been excluded from the trial and essentially are beginning their clinical trials once the medications obtain FDA approval and available on the market.



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Additionally, it is recognized that many patients with COPD are in lower socio-economic groups³ and may be far from clinical study centers. Enhanced Diversity Draft Guidance marketing efforts, describing that reimbursement for travel and associated expenses due to site visits is allowed as part of clinical trial participation—would also be very helpful, in order to overcome reluctance from some of the participants who may otherwise experience financial hardships connected with site visits.

Similarly, it is recognized that American Indians/Alaska Natives, multiracial, non-Hispanic blacks have a disproportionately high rate of COPD compared to whites.⁴ Still, most COPD studies are of white and black adults, including the very large COPD Gene study with over 10,000 patients.⁵ It is helpful that the Enhanced Diversity will try to have greater diversity of study subjects, which will be more representative of the wider population afflicted with COPD.

Conclusion

The US COPD Coalition believes that these comments only scratch the surface of the issues in having more diverse studies that better reflect the people afflicted with COPD and truly all chronic health conditions. Exclusion or under representation of persons, representing other parts of the demographic of COPD’s demographics, only tells us part of the story.

We believe we have provided enough documentation and information to support the Enhanced Diversity Draft Guidance that is being proposed and believe it is a much-needed start in the correct direction. We know that there are many medications and treatments in development for COPD and believe having a more diverse and robust study population will only provide better and richer information for patients and providers. We are happy to be contacted to provide any additional information.

Respectfully,

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¹ Centers for Disease Control and Prevention. [Chronic Obstructive Pulmonary Disease Among Adults—United States, 2011](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5914a.htm). Morbidity and Mortality Weekly Report 2012;61(46):938–43 [accessed 2019 February 13].

² <https://journal.copdfoundation.org/jcopdf/id/1233/Asthma-COPD-Overlap-Syndrome>

³ <https://www.dovepress.com/socioeconomic-status--and-copd-among-low--and-middle-income-countries-peer-reviewed-article-COPD>

⁴ <https://www.statista.com/statistics/782458/copd-prevalence-us-by-ethnicity/>

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2924193/>